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| APPLICATION NO.                                                                                              | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|--------------------------------------------------------------------------------------------------------------|-------------|----------------------|-------------------------------|------------------|
| 09/762,294                                                                                                   | 04/02/2001  | Chil-Yong Kang       | 9611-16                       | 4835             |
| 1059                                                                                                         | 7590        | 07/17/2003           |                               |                  |
| BERESKIN AND PARR<br>SCOTIA PLAZA<br>40 KING STREET WEST-SUITE 4000 BOX 401<br>TORONTO, ON M5H 3Y2<br>CANADA |             |                      | EXAMINER<br>PARKIN, JEFFREY S |                  |
|                                                                                                              |             |                      | ART UNIT<br>1648              | PAPER NUMBER     |

DATE MAILED: 07/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                          |                     |
|------------------------------|--------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b>   | <b>Applicant(s)</b> |
|                              | 09/762,294               | KANG ET AL.         |
|                              | <b>Examiner</b>          | <b>Art Unit</b>     |
|                              | Jeffrey S. Parkin, Ph.D. | 1648                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 01 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04/02/01 & 04/02/02.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-30 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |                                                                                                |                                                                              |
|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

**Unity of Invention****35 U.S.C. § 371**

1. This application was filed under 35 U.S.C. § 371 and is subject to unity of invention practice pursuant to 35 U.S.C. § 121 and 372. The regulations governing the claiming of different inventions in one national application are set forth under 37 C.F.R. § 1.141, 5 1.475, and 1.499. Applicants are reminded that if multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto, will be considered as the main 10 invention in the claims (refer to PCT Article 17(3)(a) and § 1.476(c)). The novelty of the instant invention appears to be directed towards a non-cytolytic recombinant human immunodeficiency virus wherein the natural signal sequence (NSS) has been modified or replaced. Should applicants elect to prosecute this invention, 15 a single method of use (e.g., the prevention of retroviral transmission) would also be included for examination. However, the remaining groups do not share a special technical feature with Group I as set forth below.

20 2. In accordance with 37 C.F.R. § 1.499, applicants are required, in response to this action, to elect a single invention to which the claims must be restricted.

25 a. Group I, claim(s) 1-21, drawn to a **non-cytolytic recombinant human immunodeficiency virus** wherein the natural signal sequence (NSS) has been modified or replaced and attendant method of use.

30 b. Group II, claim(s) 22-25, drawn to a **method of killing a target cell** by administering a **recombinant virus** carrying the HIV-1 NSS sequence.

- c. Group III, claim(s) 26-28, drawn to a **method of inhibiting apoptosis** induced by an HIV-1 NSS by administering an **antagonist**.
- 5 d. Group IV, claim(s) 29 and 30, drawn to a **method of inhibiting the effects of an HIV-1 NSS** through the administration of an **antisense oligonucleotide**.

The inventions listed as Groups I-IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Each of the identified groups is directed toward a different scientific objective (i.e., method of preventing retroviral infection, killing a target cell, inhibiting apoptosis, or 15 inhibiting NSS activity) that employs different scientific reagents and methodologies. Accordingly, there is no special technical feature present in the claims.

37 C.F.R. § 1.48(b)

20 3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 25 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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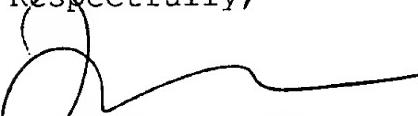
*Correspondence*

35 4. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703)

308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

5           5. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday  
10           from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the  
15           status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

10 July, 2003